

February 20, 2004

Office of Nutritional Products

Labeling and Dietary Supplements (HFS-810)

**FDA** 

P.O. Box 199 200 C Street, SW

Washington, DC 20204

RE: Notification for Statement on Dietary Supplement

Dear Sir/Madam:

110 South Garfield

In compliance with the Dietary Supplement Health and Education Act of 1994, Highland Laboratories, 110 S Garfield, PO Box 199, Mt. Angel, Oregon 97362, hereby makes its official notification under Section 101.93 that it has included a statement listed in Section 403(r)(6) of the Federal Food, Drug, Cosmetic Act on its label. Accordingly, enclosed please find two (2) copies of this Notification.

Mt. Angel, OR 97362

503-845-9223

1-800-547-0273

Company	Product Name	Dietary Ingredients	Statements
Highland Laboratories	Super Phyters <sup>TM</sup>	Beta Carotene 6 mg. Vitamin C 200 mg. Vitamin E 400 I.U. Pantothenic Acid 10 mg. Zinc 15 mg. NAC 100 mg. (n-acetyl-L-cysteine) Grape Seed Ext 60 mg. Green Tea Ext 30 mg. Alpha Lipoic Acid 15 mg. Glutathione 10 mg. Selenium 100 mcg.	Immune system support.  Super Phyters combines nutrients scientifically documented as powerful antioxidants.  Please see attachment 1

FAX 503-845-6364

975 0162 LET 13844

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## Attachment 1 Highland Laboratories

## SUPER PHYTERS™ Antioxidant Blend

You've heard the words "free radical", but do you know what it is? No, not your free-thinking neighbor who refuses to mow their lawn for various reasons; none of which you understand.

Free radicals are incomplete atoms. Complete atoms are made up of a positively charged nucleus and negatively charged electrons. Electrons normally move about in pairs. If one is separated from the other, leaving an atom made up of a nucleus and one electron, a free radical is created.

In general, free radicals are not good. You see an atom needs two electrons to operate properly. If it doesn't have two electrons, they steal one from an atom that does. Doing so causes damage to the second atom and starts a chain reaction of single electron atoms stealing from whole atoms. Every cell in your body is exposed to an estimate of over 10,000 attacks by free radicals every day. With this creation of free radicals come several health risks.

This is where our super-hero Antioxidant enters. Antioxidants are a category of vitamins, herbs, and enzymes that "neutralize" the free radicals by donating an electron to it. You would think that by doing this the antioxidant itself would become a free radical. It doesn't. That's why it's a super-hero.

Our super-hero, with bionic sight, quickly surveys the situation, and knows precisely what action to take. While out on "patrol", antioxidants help prevent the formation of excess free radicals and repair molecules that have been damaged (medic, we need a medic!) or replace the damaged molecules with new ones (Look, why don't you just call it a day. You played a valiant game kid.)

Eating a diet that includes fresh fruits and vegetables is always encouraged as they provide needed nutrients and antioxidants to help fight free-radicals.

- Beta Carotene a precursor to vitamin A and an antioxidant, it's important for the formation of teeth and bones as well as maintaining healthy epithelial tissue (the tissue that skin and mucous membranes are made of).
- Vitamin C esterified and acid free, it is the first line of antioxidant protection by neutralizing free radicals before they have a chance to harm healthy cells.<sup>2</sup>
- Vitamin E assists in protecting cell membranes from damage.
- Pantothenic Acid aids in vitamin utilization and is required by all cells in the body.
- Zinc required for proper cell division, zinc is involved in almost every aspect of immunity.<sup>3</sup>
- N-Acetylcysteine Glutathione, an antioxidant, is produced in the liver.
   It helps maintain the integrity of both red and white blood cells.

<sup>&</sup>lt;sup>1</sup> Ulene, Art MD, Dr. Art Ulene's Complete Guide to Vitamins, Minerals, and Herbs; Avery Publishing 2000, pp 25-27

<sup>&</sup>lt;sup>2</sup> Ulene, Art MD, Dr. Art Ulene's Complete Guide to Vitamins, Minerals, and Herbs; Avery Publishing 2000, pp 165-66

<sup>&</sup>lt;sup>3</sup> Murray, Michael T, N.D., Encylopedia of Nutritional Supplements Prima Publishing 1996 pp 181-86

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- N-Acetylcysteine is one of the building blocks for glutathione. It increases the level of glutathione in the lungs, kidneys, liver, and bone marrow.<sup>4</sup>
- Grape Seed Extract active ingredient is proanthocyanidin which is a powerful free radical scavenger.
- Green Tea Extract active ingredients include proanthocyanidin and epigallocatechin gallate which is a broad spectrum antioxidant.<sup>5</sup>
- Alpha Lipoic Acid an antioxidant on its own, it enhances the abilities of vitamin C, vitamin E, and glutathione.
- Glutathione a protein produced by the liver from cysteine, Glutamic acid, and glycine. Helps protect against cellular damage.<sup>6</sup>
- Selenium helps prevent the oxidation of fats. Is especially powerful when combined with vitamin E.<sup>7</sup>

Super Phyters has been synergistically formulated for the best results. As with all their products, Highland Laboratories uses only the highest quality ingredients.

These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

<sup>&</sup>lt;sup>4</sup> Balch, James F, M.D. & Balch, Phyllis A, C.N.C Prescription for Nutritional Healing Avery Publishing p 39

<sup>&</sup>lt;sup>5</sup> Weiner, Michael A PhD & Weiner, Janet Herbs that Heal Quantum Books 1994 pp 176-78
<sup>6</sup> Balch, James F, M.D. & Balch, Phyllis A, C.N.C Prescription for Nutritional Healing Avery Publishing p 42

<sup>&</sup>lt;sup>7</sup> Balch, James F, M.D. & Balch, Phyllis A, C.N.C Prescription for Nutritional Healing Avery Publishing p 28